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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/319,204 | 06/30/1999 | ROLAND DE LA METTRIE | 05725.0398 | 2598 |

7590

04/01/2003

FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER
1300 I STREET NW
WASHINGTON, DC 20005

EXAMINER

EINSMANN, MARGARET V

ART UNIT

PAPER NUMBER

1751

DATE MAILED: 04/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/319,204

Applicant(s)

DE LA METTRIE ET AL.

Examiner

Margaret Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 75-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 75-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 21, 2003 has been entered. Accordingly, the pending claims are 75-97.

Regarding the provisional obviousness double patenting rejection over application serial number 09/319,165, the rejection remains of record since no terminal disclaimer has been presented.

The rejection of claims 75 and 76 under 35 U.S.C. 103(a) as being unpatentable over Yamahatsu, EP 716,846 is withdrawn.

The rejection of claims 32-64, 67, 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotteret, U.S. 5514188 in view of Tsujino, U. S. 4,961,925 has been mooted by applicant's cancellation of said claims.

The following new grounds of rejection are applied in this office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 75-97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,241,784. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the claims of the patent are directed to compositions containing the same oxidation dyes, couplers, 2-electron oxidoreductase enzymes and donors for said enzymes as herein claimed. The patent claims differ from the instant claims in that the patent claims require at least one nonionic guar gum. Since applicant's claims are in comprising terms, this patent would anticipate the instant claims were it available as prior art.

Claims 75-97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,342,078. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims cover compositions which overlap the instant compositions as the same oxidation bases and couplers are claimed in compositions with 2-electron oxidoreductase enzymes and donors for said enzymes. The patent claims differ from the instant claims because the patent claims claim that the composition also comprises water or an organic solvent. It would have been obvious to the skilled artisan that the claims are clearly analogous as it is notoriously well known

that oxidation hair dyeing compositions are dissolved in a solvent and that said solvent is always an aqueous one.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotteret et al., US 5,514,188 in view of Tsujino, 4,961,925.

Cotteret discloses oxidative hair dyeing compositions and process of dyeing hair with said compositions comprising several of the substituted para-phenylenediamines claimed or one of the double bases as claimed in combination with additional oxidation bases and couplers. See abstract and column 2 lines 29 et seq for the description of the substituted p-phenylenediamines. All of the p-phenylenediamine compounds listed in the claims are included in patentee's formula I; most if not all of them are specifically listed in col 3 lines 1-33. The compositions may be present in the claimed amounts and are used at the claimed pH's. See col 4 line 56-col 5 line 2 and col 5 lines 34-37. The double bases are listed in col 4 lines 16-24. The compositions of the patent must contain one of the substituted p-phenylenediamines or double bases, as coupling component at least 2-methyl-5-aminophenol and at least one para-aminophenol chosen from the list in col 4 lines 31-34. The compositions are developed with the addition of oxidants, preferably hydrogen peroxide; the components are provided for sale in

multicompartment kits. Col 4 lines 40-51. In examples 1-6 Cotteret exemplifies compositions which contain dye mixtures as claimed, which are mixed with a hydrogen peroxide oxidant before application to hair. Cotteret does not teach the claimed oxidoreductase enzymes and donors.

Tsujino, US patent 4,961,925 teaches compositions for dyeing hair which contain at least one dielectron reducing oxidase using oxygen as an acceptor (that is, a 2-electron oxidoreductase enzyme as claimed), wherein Tsujino's preferred oxidases include those as claimed (e.g. uricase), se abstract; col 1, lines 46-54 and col 2 lines 37-40. The enzymes are used with a donor as claimed (e.g. uric acid), wherein the enzymes and donors may be present in the claimed amounts, se col 2 lines 1-17. Tsujino teaches that when using the claimed enzyme/donor systems, satisfactory dyeing results are achieved which have improved characteristics as compared to conventionally used oxidants (e.g. hydrogen peroxide) such as lower skin irritation and reduced damage to the hair and skin, see col 1llines 12-15 and 26-43 and Test example 1 (see also table 1). The enzyme donor systems may be combined with any conventionally used oxidation dyes, including the oxidation bases and couplers a claimed and as taught by Cotteret. See col 2 lines 45-et al. See Test Example 1 and examples 4,7,8,10,11 and 12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the hydrogen peroxide oxidants of Cotteret with an enzyme/donor system as claimed in the claimed amounts because Cotteret does not require the use of any specific oxidants, and Tsujino teaches that the claimed enzyme

/donor systems are used in place of hydrogen peroxide which contain any conventional oxidation dyes for the purpose of reducing damage to the hair and skin irritation.

Claims 75-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brody et al., US 3,884,627 in view of Tsujino, US 4,961,925.

Brody discloses oxidative hair dyeing compositions and process of dyeing hair with said compositions comprising several of the substituted para-phenylenediamines claimed in combination with additional oxidation bases and couplers. See abstract and column 1 lines 10 et seq for the description of the substituted p-phenylenediamines. Note table 1 in column 7 wherein said substituted para-phenylene diamines are mixed with other para components, coupling components, and other oxidation dye intermediates (that is oxidation bases or couplers). Turning to the description of the other oxidation bases and couplers which may be used in combination, several as claimed are listed:

Applicant's first oxidation base, 2,5-diaminopyridine, is listed in col 4 line 39;

Applicant's first claimed oxidation base, o-aminophenols, are listed in col 5 line 32;

Applicant's second claimed oxidation base, p-aminophenol, is listed in col 4 lines 36-37;

Applicant's claimed coupler components, m-aminophenols, are listed in col 5 lines 6-14.

Accordingly, Brody teaches mixtures comprising three of applicant's claimed first oxidation bases, applicant's claimed second oxidation base and applicant's claimed couplers. Brody teaches that said dye mixtures are mixed with an oxidant and applied to the hair in the claimed amounts to obtain a variety of shades. See examples. The oxidant is a hydrogen peroxide developer. Brody does not teach the claimed oxidoreductase enzymes and donors.

Tsujino, US patent 4,961,925 teaches compositions for dyeing hair which contain at least one dielectron reducing oxidase using oxygen as an acceptor (that is, a 2-electron oxidoreductase enzyme as claimed), wherein Tsujino's preferred oxidases include those as claimed (e.g. uricase), se abstract; col 1, lines 46-54 and col 2 lines 37-40. The enzymes are used with a donor as claimed (e.g. uric acid), wherein the enzymes and donors may be present in the claimed amounts, se col 2 lines 1-17. Tsujino teaches that when using the claimed enzyme/donor systems, satisfactory dyeing results are achieved which have improved characteristics as compared to conventionally used oxidants (e.g. hydrogen peroxide) such as lower skin irritation and reduced damage to the hair and skin, see col 1 lines 12-15 and 26-43 and Test example 1 (see also table 1). The enzyme donor systems may be combined with any conventionally used oxidation dyes, including the oxidation bases and couplers a claimed and as taught by Brody. See col 2 lines 45 et al. where at least the following dyes disclosed by Brody are included in the list of dyes specifically disclosed by Tsujino: p-aminophenol, o-aminophenol, m-aminophenol and acid addition salts thereof.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the hydrogen peroxide oxidants of Brody with an enzyme/donor system as claimed in the claimed amounts because Brody does not require the use of any specific oxidants except that the oxidant is preferably hydrogen peroxide and Tsujino teaches that the claimed enzyme /donor systems are used in place of hydrogen peroxide to produce a peroxide which is milder than hydrogen peroxide in hair dyeing systems which contain any conventional oxidation dyes for the purpose of reducing damage to the hair and skin irritation.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Margaret Einsmann whose telephone number is 703-308-3826. The examiner can normally be reached on 7:00 AM -4:30 PM M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 703-308-4708. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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Margaret Einsmann
Primary Examiner
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March 24, 2003